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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,178	10/28/2003	J. Daniel Raulerson	MED0065	4287
33941	7590	10/29/2009	EXAMINER	
Fox Rothschild LLP Blue Bell 2000 Market Street Tenth Floor Philadelphia, PA 19103			VU, QUYNH-NHU HOANG	
			ART UNIT	PAPER NUMBER
			3763	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/695,178	<b>Applicant(s)</b> RAULERSON ET AL.	
	<b>Examiner</b> QUYNH-NHU H. VU	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 24 July 2009.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 34-38 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 34-38 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \*    c)  None of:
1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/4/09</u> . | 6) <input type="checkbox"/> Other: _____  |

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## DETAILED ACTION

### *Response to Amendment*

Amendment and Request for Continued Examination (RCE) filed on 07/24/09 have been entered.

Claims 34-38 are present for examination.

Claims 1-33 are cancelled.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "portion of the proximal end regions of the first and second catheters extend through the hub member and proximally beyond the proximal end thereof..." is vague.

Does Applicant mean that the proximal end of hub member or the proximal end region of catheters?

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash et al. (US 5,947,953) in view of Markel et al. (US 5,624,413) or Martin (US 4,682,978).

Ash discloses a multiple catheter assembly, comprising:

a first catheter 26 having a first distal end region and a first proximal end region joined by a first intermediate section;

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a second catheter 30 having a second distal end region and a second proximal end region joined by a second intermediate section;

first and second extension tube assemblies 84, 90 having first and second distal end portions respectively associated with the first and second proximal end regions of the first and second catheters; and

a hub member 24 is capable/adapted to be releasably attachable to and around the first and second proximal end regions of the first and second catheters distally of the proximal ends thereof, after catheter implantation and subcutaneous tunneling and at a site selectable by the practitioner.

*It has been held that the recitation that the hub member is "adapted to/capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.*

*Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. after catheter implantation and subcutaneous tunneling... to respective medical devices, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).*

Ash does not disclose that portions of the proximal end regions of the first and catheter extend through the hub member and proximally beyond the proximal end of the hub member thereof to be connected to respective medical devices.

Market shows that the portion end regions of the first and second catheters 22, 24 extend through the hub member 90 (Figs. 6-7) and proximally beyond the proximal end of hub member thereof to be connected to respective ones of the first and second extension tube assemblies 76.

Alternatively, Martin shows that the portion end regions of the first and second catheters 46 extend through the hub member 28 (Fig. 12) and to be connected to respective ones of the first and second extension tube assemblies 30, 32. Although, Martin does not show that the proximal end of first and catheter stopped at the proximal end of hub member 28 instead of

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proximally beyond the proximal end of hub member. However, the proximal end of catheters stopped at proximal end of hub member is an equivalent structure essential working parts of a device involves only routine skill in the art.

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Ash with the catheters extend beyond the hub member, as taught by Market or Martin, in order to connect with extension tube assembly.

Regarding claims 35, wherein the cross-sectional shapes of the first and second proximal end regions is circular (col. 7, lines 30-38), and the cross-sectional shapes of the first and second distal end portions of the first and second extension tubes is circular is very well-known in the catheter art.

Regarding claim 36, wherein the cross-sectional shapes of the first and second intermediate sections of the first and second catheters is semicircular (Fig. 4F), and the first and second catheters have transition sections between the circular cross-sectional shapes of the first and second proximal and distal end regions and the semicircular cross-sectional shapes of the first and second intermediate sections.

Regarding claim 37, wherein the first and second intermediate sections of the first and second catheters are splittably joined to each other by element 46.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash et al. in view of Markel et al. or Martin and further in view of Cazal (US 5,800,414).

Ash et al. in view of Markel et al. or Martin discloses the invention substantially as claimed.

Ash et al. in view of Markel et al. or Martin discloses the first and second intermediate sections of the first and second catheter are splittably joined to each other by member 46. Ash et al. in view of Markel et al. or Martin does not disclose the splittably joined to each other by adhesive.

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Cazal discloses a similar device, in which the first and second catheters are splittably joined to each other by adhesive 14 or 20. As note that, the adhesive 14 or 20 is capable of splittably if using the force to tear it.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Ash et al. in view of Markel et al. or Martin, with an adhesive, as taught by Cazal, in order to join the two catheters.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/974,267.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they device of instant claims are fully disclosed and covered by the claims in the copending application claims.

As noted that, claims 1-37 does not include the hub or an initially separate hub. However, the Applicant admitted that the hub 150 may be omitted is common sense or well-known in the art (see para 0036 of Specification or para 0050 of Application 10/974267). Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to the releasable hub, since it has been held that omission of an element and its function in

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a combination where the remaining elements perform the same functions as before involves only routine skill in the art.

***Response to Arguments***

Applicant's arguments with respect to claims 34-38 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763